

REMARKS

Reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested in view of the remarks herewith.

The May 6, 2003 Office Action called for restriction from among the following:

- Group I: Claims 6-20, drawn to composition comprising compounds of the claimed formula wherein the polycycle moiety is a steroid moiety, classified in class 514, subclass 169+; and
- Group II: Claims 6-20, drawn to composition comprising compounds of the claimed formula wherein the polycycle moiety is a non-steroid moiety, classified in class 514, subclass 183+.

Group I is elected, with traverse, for further prosecution in this application. Applicants reserve the right to file divisional applications to non-elected subject matter. Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

The May 6, 2003 Office Action also required election of a single disclosed species under 35 U.S.C. § 121 from under the elected Group for search purposes. Applicants elect oestrone-3-sulphamate, with traverse. Reconsideration and withdrawal of the species election are respectfully requested in view of the remarks herewith.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional inventions must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions.” *Id.*

The Office Action States that Groups I and II are drawn to compositions comprising structurally different compounds, i.e., steroidal and non-steroidal compounds.

It is respectfully submitted that any search for the compositions of the Group I claims will certainly encompass references for the compositions of the Group II claims, i.e., methods of treating a patient employing the composition of the Group I claims. The two groups are inextricably linked in that the compositions of both groups are inhibitors of an enzyme having steroid sulphatase activity and that the sulphamate group on the compound is an active

component in both groups. The search for inhibitors of an enzyme having steroid sulphatase activity having a sulphamate group would encompass both steroidal and non-steroidal polycyclic moieties. The compositions wherein the polycycle moiety is a steroid moiety (Group I) would require the same consideration as compositions wherein the polycycle moiety is a non-steroid moiety (Group II). Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine both groups together, as a search for the Group I compositions would necessarily include the Group II compositions.

Applicants respectfully direct the Examiner to U.S. application Serial No. 09/238,345, filed January 27, 1999, now issued as U.S. Patent No. 6,187,766 ("the '766 patent"), to which this application claims priority. The claims of the '766 patent are directed to pharmaceutical compositions of both steroidal compounds (claim 3 of the '766 patent) and non-steroidal compounds (encompassed in claims 1 and 2 of the '766 patent). Again, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine both groups together.

In view of the above, reconsideration and withdrawal of the restriction requirement is respectfully requested.

Furthermore, the Examiner is respectfully requested to review M.P.E.P. § 808.01(a), which states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

In view of the above, reconsideration and withdrawal of the election of species requirement are requested.

In summary, enforcing the present restriction and election requirements would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made. Indeed, the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire

application can be made without undue burden on the Examiner, especially as the claims of all Groups have identical classifications. Furthermore, the election requirement has not been shown to be proper, especially since there are relationships among the species. All of the preceding, therefore, mitigate against restriction.

Consequently, reconsideration and withdrawal of the restriction and election of species requirement are respectfully requested.

CONCLUSION

In view of the amendments and remarks herein, reconsideration and withdrawal of the restriction requirement and election of species, are requested.

Early and favorable consideration of the application on the merits, and early Allowance of the application are earnestly solicited.

Respectfully submitted,
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